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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/689,861 | 10/20/2003 | Yanbin Liang | 17564 (AP) | 3763 |
| 51957 | 7590 | 02/07/2006 | EXAMINER | |
| ALLERGAN, INC., LEGAL DEPARTMENT 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599 | | | HOWARD, ZACHARY C | |
| | | | ART UNIT | PAPER NUMBER |

1646

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/689,861 | Applicant(s) LIANG ET AL. | |
| | Examiner Zachary C. Howard | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 11/7/05 has been entered in full. Claim 5 is amended. Claims 1-4 and 7-53 are canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5 and 6 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

The following page numbers refer to the previous Office Action (6/6/05).

The objection to claims 5 and 6 at pg 2 is *withdrawn*. This objection should not have been made, because claims 5 and 6 were included in the rejection under 35 USC § 101 for lack of utility (see pg 2-4 of the 6/6/05 Office Action). The Examiner apologizes for inadvertently including this objection in the Office Action.

All rejections of claims 1-4 and 7 are *withdrawn* in view of Applicants' cancellation of these claims.

Please see new rejection of claims 5 and 6 under 35 USC § 112, 1st paragraph below.

Claim Rejections - 35 USC § 101, utility

Claims 5 and 6 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. This rejection was set forth at pg 2-4 of the 6/6/05 Office Action.

Applicants' arguments (11/7/05; pg 3) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 11/7/05, Applicants submit that the 6/6/05 Office Action stated at pg 2 that claims 5 and 6 would be allowable if rewritten in independent form.

Applicants submit that the amendments to the claims place the case in condition for allowance.

Applicants' arguments have been fully considered but are not found persuasive. The Examiner inadvertently included the objection to claims 5 and 6 that indicated they would be allowable if rewritten in independent form. However, both claims 5 and 6 were included in the rejection under 35 USC § 101 for lack of utility at pg 2-4 of the 6/6/05 Office Action. Furthermore, the Office Action Summary (pg 1 of the Office Action) indicated that claims 5 and 6 were rejected. Therefore, the rejection of claims 5 and 6 for lack of utility is maintained for the reasons previously set forth and reiterated below.

Claims 5 and 6 are each directed to an isolated polypeptide. The specification teaches that the claimed polypeptide of SEQ ID NO: 2 is a prostaglandin D2 receptor splice variant. The prior art reports that the full-length prostaglandin DP receptor is a G-protein coupled receptor (GPCR) that binds prostaglandin PGD1 and PGD2. The prior art further teaches the DP receptor is a relaxant receptor that mediates increases in cAMP and induces smooth muscle relaxation (Kobayashi et al, 2000; cited in the 6/6/05 Office Action) No well-established utility exists for splice variants of previously characterized prostaglandin receptors. The prior art teaches that many splice variants of other prostaglandin (prostanoid) receptors have been identified. The prior art teaches, "Another striking feature of the prostanoid receptor family is the existence of alternatively spliced messenger RNA (mRNA) variants described for four of the eight PG GPCRs, the TP, FP, EP1, and EP3 receptors. In each case, the alternative splicing occurs in the intracellular C-terminal region of the receptor. Alternative splicing does not appear to affect the ligand-binding properties of the receptor, but it does have impact on G-protein coupling specificity and constitutive activity, as well as agonist-induced receptor phosphorylation, desensitization, and/or internalization" (see page 668 of Breyer et al, 2001; cited in the 6/6/05 Office Action) Breyer further teaches (pg 671) that both splice variants of the FP receptor exhibit constitutive signaling activity, whereas Breyer teaches (pg 672) that a splice variant of the EP1 receptor binds ligand but "does not elicit detectable signal transduction". Therefore, although these variants share a common structural feature (a splicing event in the C-terminal region of the mRNA

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encoding the protein), this common structural feature does not indicate that the splice variant functions in a manner similar to the full-length parent polypeptide. Therefore, even if the parent prostaglandin receptor has an identified specific and substantial utility, a novel splice variant of such a receptor would not necessarily have a specific and substantial utility.

The specification asserts that the claimed prostaglandin D2 receptor splice variant has a specific and substantial patentable utility in that the receptor can be used in a method of screening for compounds that modulate the receptor activity or for compounds that specifically bind to the receptor. The specific further asserts that a compound identified by such a method can be used to treat a disease associated with a DP receptor or receptor variant.

The proposed use of the receptor variant to screen for binding or modulating agents is not a substantial utility. A substantial utility is a practical use which amounts to more than a starting point for further research and investigation and does not require or constitute carrying out further research to identify or reasonably confirm what the practical use might ultimately be. The specification teaches (pg 75-77) screening assays in which the receptor can be used, but does not teach disclose or specify a specific disease that is associated with the receptor variant.

An assay that screens for a compound that modulates the activity of a receptor that has a stated correlation to a predisposition to the onset of a particular disease condition would be a practical use of the material. However, a method of screening with a material that has no particular correlation with a disease does not constitute a substantial utility. Basic research, such as studying the properties of the claimed product or the mechanisms in which the product is involved, does not constitute a substantial utility. Furthermore, the specification does not teach any particular activity or physiological function of the receptor variant.

The specification does not put forth that the prostaglandin D2 receptor variant is involved in any specific disease states, and could therefore be used as a diagnostic or therapeutic agent. A stated belief that a correlation exists between the channel and any number of diseases is not sufficient guidance to use the claimed polynucleotides to treat

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and/or diagnosis a particular disease; it merely defines a starting point for further research and investigation.

In summary, the instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a specific or substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed nucleic acids.

Claim Rejections - 35 USC § 112, 1st paragraph, enablement

Claims 5 and 6 are also rejected under 35 U.S.C. § 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Bridget C. Bunner

**BRIDGET BUNNER
PATENT EXAMINER**